DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1077d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER
FINAL LETTER

March 7, 2001

Certified Mail
Return Receipt Requested

Susan Spieller
Director of Radiology
Orange Imaging Medical Group
293 South Main Street; Suite 100
Orange, CA 92868

W/L Number: 23 - 01
Inspection ID: 1291710006
CFN: 20-29,627
FEI Number: 1000518950

Dear Ms Spieller:

We are writing to you because on January 3, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

- Level 1: Mammograms were processed in processor #1 (a [redacted] machine, model [redacted]), located in the darkroom, when said machine was out of limits on 8 days since the previous inspection on November 23, 1999.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation

of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

On January 15, 2001, [redacted] (Orange County Regional Operations Manager at RadNet Management, Inc.) responded by letter to the noncompliances found during the inspection. Based on your response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next inspection.

Should any additional communication on this matter be necessary, please submit your letter to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

re: Warning Letter #23 – 01
re: Orange Imaging Medical Group

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit
550 South Vermont Avenue; suite #601
Los Angeles, CA 90020